

Applicants: Ron S. Israeli et al.
Serial No.: 08/466,381
Filed : June 6, 1995
Page 4

The Examiner stated that the specification discloses SEQ ID NO. 2 which corresponds to the nucleic acid sequence encoding the prostate specific antigen having the amino acid sequence shown in SEQ ID NO.2. The Examiner stated that this SEQ ID NO. 2. meets the written description and enablement provisions of 35 U.S.C. §112, first paragraph. The Examiner stated that the claims are directed to encompass a nucleic acid molecule (i.e. primer) that hybridize to the nucleic acid sequence encoding the prostate specific antigen having the amino acid sequence shown in SEQ ID NO. 2 or other sequences, which correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have similarity or homology, and so forth. The Examiner stated that none of these nucleic acid molecule (i.e. primer) or nucleic acid molecules encoding a prostate specific membrane antigen meet the written description provisional of 35 C.F.R. 112, first paragraph.

The Examiner stated that Vas-Cath Inc. V. Makurhar, 19 USPQ2d 1111, makes clear that the applicant must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in possession of the invention. The Examiner stated that the invention is, for purpose of the written description inquiry whatever is now claimed (see page 1117). The Examiner stated that the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

The Examiner stated that with the exception of SEQ ID NO.2 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotide and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. The Examiner stated that adequate written description requires more than a mere statement that is part of the invention and reference

Applicants: Ron S. Israeli et al.
Serial No.: 08/466,381
Filed : June 6, 1995
Page 5

to a potential method for isolating it. The nucleic acid itself is required.

In response but without conceding the correctness of the Examiner's position and to expedite the prosecution of the subject application applicants have amended claims 90-93 to incorporate SEQ ID NO. 2 according to the Examiner's recommendations.

Further, applicants maintain that the claimed invention has been fully enabled by the specification as filed. Applicants' claimed invention is directed to a method of detecting a micrometastatic prostate tumor cell of a subject. Applicants have provided a detailed description of one such method in the specification pages 86-95 entitled, "Sensitive Detection Of Prostate Hematogenous Micrometastases Using PSA and PSM-Derived Primers in the Polymerase Chain Reaction". Accordingly, applicants believe that the requirements for section 112, first paragraph has been satisfied and respectfully request the reconsideration and withdrawal of the above ground rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants: Ron S. Israeli et al.
Serial No.: 08/466,381
Filed : June 6, 1995
Page 6

No fee, except for a fee of \$475.00 for a three-month extension of time is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-1325.

Respectfully submitted,

Albert Wai Kit Chan

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.	
<u>Albert Wai Kit Chan</u>	<u>2/9/98</u>
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